

902 KAR 20:260. Hospital-owned pain management clinics.

RELATES TO: KRS 198B.260, 216B.010-216B.131, 216B.990, 218A.175, 218A.205, 311, 314, 29 C.F.R. 1910.1030(d)(2)(viii), 45 C.F.R. 160, 164, 21 U.S.C. 801 – 971, 42 U.S.C. 1320d-2 - 1320d-8

STATUTORY AUTHORITY: KRS 13A.100, 216B.042, 216B.105

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042 and 216B.105 require the Cabinet for Health and Family Services to promulgate administrative regulations governing health facilities and health services. This administrative regulation establishes the minimum licensure requirements for the operation of a pain management clinic if the clinic's primary practice component is the treatment of pain using controlled substances, and the clinic is located off the campus of the hospital that has majority ownership interest.

Section 1. Definitions. (1) "Diagnostic services" means services that are performed to ascertain and assess an individual's physical health condition.

(2) "License" means an authorization issued by the cabinet for the purpose of operating a hospital-owned pain management clinic.

(3) "Unencumbered license" means a prescriber's license that has not been restricted by the state professional licensing board due to an administrative sanction or criminal conviction relating to a controlled substance.

Section 2. Scope of Operations and Services. A Kentucky-licensed hospital that is excluded from the definition of pain management facility pursuant to KRS 218A.175(1)(b) shall obtain separate licensure under this administrative regulation for any outpatient clinic owned and operated by the hospital if:

(1) The majority of the patients of the practitioners at the clinic are provided treatment for pain that includes the use of controlled substances; and

(2) The clinic is located off-campus.

Section 3. Administration Requirements. (1) Administration.

(a) A hospital that owns and operates a pain management clinic shall be legally responsible for the clinic's compliance with federal, state, and local laws and administrative regulations pertaining to the operation of the facility, including the Drug Abuse Prevention and Control Act (21 U.S.C. 801 to 971 et. seq.), KRS Chapter 218A, 902 KAR Chapter 20, and 902 KAR Chapter 55.

(b) A licensee shall establish lines of authority and designate an administrator who shall be principally responsible for the daily operation of the clinic.

(2) Policies. A clinic shall establish and follow written administrative policies covering all aspects of operation, including:

(a) A description of organizational structure, staffing, and allocation of responsibility and accountability;

(b) A description of linkages with inpatient facilities and other providers;

(c) Policies and procedures for the guidance and control of personnel performances;

(d) A written program narrative describing in detail the:

1. Services offered;

2. Methods and protocols for service delivery;

3. Qualifications of personnel involved in the delivery of the services; and

4. Goals of the services;

(e) A description of the administrative and patient care records and reports;

(f) Procedures to be followed if an individual seeks or is in need of care and treatment that is beyond the scope of services offered by clinic, which may include:

1. Advising the individual to seek services elsewhere;
2. Making a referral on behalf of the individual; or
3. Contacting emergency medical services; and

(g) Procedures to be followed if the clinic performs any functions related to the storage, handling, and administration of drugs and biologicals.

(3) Patient care policies. The clinic's medical director shall develop patient care policies in collaboration with a group of the clinic's other professionals to address all medical aspects of the clinic's program, including:

(a) A description of the services the clinic provides directly and those provided through agreement;

(b) Guidelines for the medical management of health problems, which include the conditions requiring medical consultation or patient referral;

(c) Guidelines for the maintenance of medical records in accordance with subsection (6) of this section; and

(d) Procedures for review and evaluation of the services provided by the clinic at least annually.

(4) Personnel.

(a) Medical director. A clinic's medical director:

1. Shall meet the requirements of Section 6(3) and (4) of this administrative regulation;
2. Shall provide direct services, supervision, and consultation to the clinic's staff;
3. Shall participate with a group made up of clinic professionals, including at least one (1) nurse, in the development of:

a. Execution and periodic review of the clinic's written policies and services as described in subsection (3) of this section; and

b. Written program narrative describing in detail:

- (i) Each service offered;
- (ii) Methods and protocols for service delivery;
- (iii) Qualifications of personnel involved in the delivery of the services; and
- (iv) Goals of each service;

4. Shall periodically review the clinic's patient records, provide medical orders, and provide medical care services to patients of the clinic; and

5. May serve as both the clinic's administrator and medical director.

(b) The clinic shall:

1. Employ, directly or by contract, a sufficient number of qualified personnel (e.g., physicians, nurses, therapists, or technicians) to provide effective patient care and all other related services; and

2. Maintain written personnel policies that are made available to all employees.

(c) There shall be a written job description for each position that shall be reviewed and revised as necessary.

(d) Current personnel records shall be maintained for each employee and include the following:

1. Name, address, and Social Security number;
2. Evidence of current registration, certification, or licensure of personnel;
3. Records of training and experience; and
4. Records of performance evaluation.

(5) In-service training. All personnel shall participate in annual in-service training programs relating to their respective job activities, including thorough job orientation for new employees.

(6) Medical records.

(a) The clinic shall maintain accurate, readily accessible, and complete medical records, which contain at least the following:

1. Medical or social history relevant to the services provided, including data obtainable from other providers;
2. Name of the patient, referring practitioner, if any, and practitioner's orders for special diagnostic services;
3. Date and description of each medical visit or contact, to include condition or reason necessitating visit or contact, assessment, diagnosis, services provided, names of personnel who provided the services, medications and treatments prescribed, and disposition made;
4. Reports of all physical examinations and laboratory and other test findings relevant to the services provided; and
5. Documentation of all referrals made, including reason for referral, to whom patient was referred, and any information obtained from referral source.

(b) Medical records shall be the property of the clinic.

(c) The original medical record shall not be removed from the clinic except in compliance with a court order or subpoena.

(d) Copies of a medical record or portions of the record may be used and disclosed, in accordance with this administrative regulation.

(e) Confidentiality/Security; Use and Disclosure.

1. The clinic shall maintain the confidentiality and security of medical records in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164, as amended, including the security requirements mandated by subparts A and C of 45 C.F.R. Part 164, or as provided by applicable federal or state law.

2. The clinic may use and disclose medical records. Use and disclosure shall be as established or required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164, or as established in this administrative regulation.

3. This administrative regulation shall not be construed to forbid the clinic from establishing higher levels of confidentiality and security than required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164.

(f) Transfer of records. The clinic shall:

1. Establish systematic procedures to assist in continuity of care if the patient moves to another source of care; and
2. Upon proper release, transfer medical records or an abstract if requested.

(g) Retention of records. After the patient's death or discharge, the complete medical record shall be placed in an inactive file and retained for:

1. Six (6) years; or
2. If a minor, three (3) years after the patient reaches the age of majority under state law, whichever is longer.

(h) The clinic shall:

1. Make provisions for the written designation of a specific location for the storage of medical records if the clinic ceases to operate because of disaster or for any other reason; and
2. Safeguard the record and its content against loss, defacement, and tampering.

(7) Kentucky Health Information Exchange (KHIE).

(a) A clinic shall participate in the KHIE pursuant to the requirements of 900 KAR 9:010.

(b) If a clinic has not implemented a certified electronic health record, the clinic may meet the requirement of paragraph (a) of this subsection by participating in the direct secure messaging service provided by KHIE.

(8) Quality assurance program.

(a) Each clinic shall have an ongoing quality assurance program that:

1. Monitors and evaluates the quality and appropriateness of patient care;
2. Evaluates methods to improve patient care;
3. Identifies and corrects deficiencies within the clinic;
4. Alerts the designated physician or prescribing practitioner to identify and resolve recurring problems; and
5. Provides for opportunities to improve the clinic's performance and to enhance and improve the quality of care provided to patients.

(b) The medical director shall ensure that the quality assurance program includes the following components:

1. The identification, investigation, and analysis of the frequency and causes of adverse incidents to patients;
2. The identification of trends or patterns of incidents;
3. The development and implementation of measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients; and
4. The documentation of these functions and periodic review no less than quarterly of this information by the designated physician or prescribing practitioner.

Section 4. Provision of Services. (1) Equipment used for direct patient care by a clinic shall comply with the following:

(a) The licensee shall establish and follow a written preventive maintenance program to ensure that equipment shall be operative and properly calibrated;

(b) All personnel engaged in the operation of equipment shall have adequate training and be currently licensed, registered, or certified in accordance with applicable state statutes and administrative regulations; and

(c) There shall be a written training plan for the adequate training of personnel in the safe and proper usage of the equipment.

(2) Diagnostic services shall be performed in accordance with the clinic's protocol.

(3) Diagnostic services shall be provided under the supervision of a physician who is qualified by advanced training and experience in the use of the specific technique utilized for diagnostic purposes.

(4) Physical examination services shall be nonabusive and provided in a manner that ensures the greatest amount of safety and security for the patient.

(5) Personnel performing a physical examination shall:

(a) Have adequate training and be currently licensed, registered, or certified in accordance with applicable Kentucky statutes and administrative regulations; and

(b) Be limited by the relevant scope of practice of state licensure.

(6) At least one (1) physician and one (1) advanced practice registered nurse, licensed practical nurse, or registered nurse shall be on duty in the clinic during all hours the facility is operational.

Section 5. Physical environment. (1) Accessibility. The clinic shall meet requirements for making buildings and facilities accessible to and usable by persons with a disability pursuant to KRS 198B.260 and administrative regulations promulgated thereunder.

(2) Fire safety. An initial license to operate a clinic or a new license to operate a clinic upon approval of a change of location shall not be issued before the clinic obtains approval from the State Fire Marshal's office.

(3) Housekeeping and maintenance services.

(a) Housekeeping.

1. The clinic shall maintain a clean and safe facility free of unpleasant odors.
2. Odors shall be eliminated at their source by prompt and thorough cleaning of commodes, urinals, bedpans, and other sources.

(b) Maintenance. The premises shall be well kept and in good repair. Requirements shall include:

1. The clinic shall ensure that the grounds are well kept and the exterior of the building, including the sidewalks, steps, porches, ramps, and fences, is in good repair;
2. The interior of the building including walls, ceilings, floors, windows, window coverings, doors, plumbing, and electrical fixtures shall be in good repair. Windows and doors that can be opened for ventilation shall be screened;
3. Garbage and trash shall be stored in areas separate from those used for the preparation and storage of food and shall be removed from the premises regularly. Containers shall be cleaned regularly; and
4. A pest control program shall be in operation in the clinic. Pest control services shall be provided by maintenance personnel of the facility or by contract with a pest control company. The compounds shall be stored under lock.

(4) The clinic shall develop written infection control policies that are consistent with Centers for Disease Control guidelines and include the:

(a) Prevention of disease transmission to and from patients, visitors, and employees, including:

1. Universal blood and body fluid precautions;
 2. Precautions against airborne transmittal of infections;
 3. Work restrictions for employees with infectious diseases; and
 4. Cleaning, disinfection, and sterilization methods used for equipment and the environment;
- and

(b) Provision of in-service education programs annually on the cause, effect, transmission, prevention, and elimination of infections.

(5) Hazardous cleaning solutions, compounds, and substances shall be:

- (a) Labeled;
 - (b) Stored in closed metal containers;
 - (c) Kept separate from other cleaning materials; and
 - (d) Kept in a locked storage area apart from the exam room.
- (6) The facility shall be kept free from insects and rodents and their nesting places.

(7) Garbage and trash:

- (a) Shall be removed from the premises regularly; and
- (b) Containers shall be cleaned daily.

(8) A clinic shall establish and maintain a written policy for the handling and disposal of wastes, including any infectious, pathological, or contaminated wastes, which shall include the requirements established in this subsection.

(a) Sharp wastes, including broken glass, scalpel blades, and hypodermic needles, shall be segregated from other wastes and placed in puncture-resistant containers immediately after use.

(b) A needle or other contaminated sharp waste shall not be recapped, purposely bent, broken, or otherwise manipulated by hand as a means of disposal except as permitted by the Centers for Disease Control and the Occupational Safety and Health Administration guidelines at 29 C.F.R. 1910.1030(d)(2)(vii).

(c) A sharp waste container shall be incinerated on or off-site or rendered nonhazardous.

(d) Any nondisposable sharp waste shall be placed in a hard walled container for transport

to a processing area for decontamination.

(9)(a) Disposable waste shall be:

1. Placed in a suitable bag or closed container so as to prevent leakage or spillage; and
2. Handled, stored, and disposed of in a way that minimizes direct exposure of personnel or patients to waste materials.

(b) The clinic shall establish specific written policies regarding handling and disposal of waste material.

(10) A licensee owned or operated incinerator used for the disposal of waste shall be in compliance with all applicable Kentucky statutes and administrative regulations.

Section 6. Standards for prescribing and dispensing controlled substances. (1) All licensed prescribers of a clinic authorized to prescribe or dispense controlled substances shall comply with the professional standards relating to the prescribing and dispensing of controlled substances established by their professional licensing boards, including 201 KAR 9:260 and 201 KAR 20:057.

(2) A representative from the Office of Inspector General shall review the clinic's records, including the clinic's patient records, to verify facility compliance with administrative regulations promulgated by professional licensing boards pursuant to KRS 218A.205 that establish standards for licensees authorized to prescribe or dispense controlled substances.

(3) A clinic shall not contract with or employ a physician or prescribing practitioner:

- (a) Whose Drug Enforcement Administration number has ever been revoked;
- (b) Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction;
- (c) Who has had any disciplinary limitation placed on his or her license by:
 1. The Kentucky Board of Medical Licensure;
 2. The Kentucky Board of Nursing;
 3. The Kentucky Board of Dentistry;
 4. The Kentucky Board of Optometric Examiners;
 5. The State Board of Podiatry;
 6. Any other board that licenses or regulates a person who is entitled to prescribe or dispense controlled substances to humans; or
 7. A licensing board of another state if the disciplinary action resulted from illegal or improper prescribing or dispensing of controlled substances; or
- (d) Who has been convicted of or pleaded guilty or nolo contendere to, regardless of adjudication, an offense that constitutes a felony for receipt of illicit and diverted drugs, including a controlled substance listed as Schedule I, Schedule II, Schedule III, Schedule IV, or Schedule V in this state or the United States.

(4) The clinic's medical director shall:

- (a) Be board certified and have a full, active, and unencumbered license to practice medicine in the commonwealth issued under KRS Chapter 311;
- (b) Be physically present practicing medicine in the clinic for at least fifty (50) percent of the time that patients are present in the clinic;
- (c) Within ten (10) days after the clinic hires a prescriber of controlled substances or ten (10) days after termination of a prescriber of controlled substances, notify the cabinet in writing and report the name of the prescriber; and
- (d) Meet one (1) of the following:

1. Hold a current subspecialty certification in pain management by a member board of the American Board of Medical Specialties, or hold a current certificate of added qualification in pain management by the American Osteopathic Association Bureau of Osteopathic Special-

ists;

2. Hold a current subspecialty certification in hospice and palliative medicine by a member board of the American Board of Medical Specialties or hold a current certificate of added qualification in hospice and palliative medicine by the American Osteopathic Association Bureau of Osteopathic Specialists;

3. Hold a current board certification by the American Board of Pain Medicine;

4. Hold a current board certification by the American Board of Interventional Pain Physicians; or

5. Have completed a fellowship in pain management or an accredited residency program that included a rotation of at least five (5) months in pain management.

(5) The clinic shall, within ten (10) calendar days after termination of the medical director, notify the cabinet of the identity of the individual designated as medical director, including the identity of any interim medical director until a permanent director is secured for the clinic.

(6) Each licensed physician who prescribes or dispenses a controlled substance to a patient in the clinic as part of his or her employment agreement with the clinic shall successfully complete a minimum of ten (10) hours of Category I continuing medical education in pain management during each registration period throughout his or her employment agreement with the clinic.

Section 7. Denial and Revocation. (1) The cabinet shall deny a clinic's application, incorporated by reference in 902 KAR 20:008, Section 9(1)(e), if:

(a) The clinic has been discontinued from participation in the Medicaid Program due to fraud or abuse of the program;

(b) An administrative sanction or criminal conviction relating to controlled substances has been imposed on the clinic or any individual under contract or employed directly by the clinic for an act or omission done within the scope of the clinic's license or the individual's employment; or

(c) The applicant fails, after the initial inspection, to submit an acceptable plan of correction or fails to submit an acceptable amended plan of correction within the timeframes required by 902 KAR 20:008, Section 2(13).

(2) If, during the initial inspection of the clinic, the cabinet has probable cause to believe that a physician or other prescriber practicing at the facility may be engaged in the improper, inappropriate, or illegal prescribing or dispensing of a controlled substance, the cabinet shall:

(a) Refer the physician or other prescriber practicing at the clinic to the appropriate professional licensing board and appropriate law enforcement agency; and

(b) Withhold issuing a license to the clinic pending resolution of any investigation into the matter by a licensing board or law enforcement agency, and resolution of the appeals process, if applicable.

(3) The cabinet shall revoke a clinic's license if it finds that:

(a) In accordance with KRS 216B.105(2), there has been a substantial failure by the clinic to comply with the provisions of this administrative regulation;

(b) An administrative sanction or criminal conviction relating to controlled substances is imposed on the clinic or any individual employed by the clinic for an act or omission done within the scope of the clinic's license or the individual's employment;

(c) The clinic fails to submit an acceptable plan of correction or fails to submit an acceptable amended plan of correction within the timeframes required by 902 KAR 20:008, Section 2(13); or

(d) The clinic is terminated from participation in the Medicaid program pursuant to 907 KAR 1:671.

(4)(a) The denial or revocation of a clinic's license shall be mailed to the applicant or licensee by certified mail, return receipt requested, or by personal service.

(b) Notice of the denial or revocation shall set forth the particular reasons for the action.

(5) The denial or revocation shall become final and conclusive thirty (30) days after notice is given unless the applicant or licensee, within the thirty (30) day period, files a request in writing for a hearing with the cabinet.

(6) Urgent action to suspend a license.

(a) The cabinet shall take urgent action to suspend a clinic's license if the cabinet has probable cause to believe that:

1. The continued operation of the clinic would constitute a danger to the health, welfare, or safety of the facility's patients; or

2. A physician or other prescriber practicing at the clinic may be engaged in the improper or inappropriate prescribing or dispensing of a controlled substance.

(b) 1. The clinic shall be served with notice of the hearing on the urgent suspension to be held no sooner than twenty (20) days from the delivery of the notice.

2. Notice of the urgent suspension shall set forth the particular reasons for the action.

(c) If the cabinet issues an urgent suspension of the clinic's license pursuant to paragraph (a)2. of this subsection, the cabinet shall refer the physician or other prescriber practicing at the clinic to the appropriate professional licensing board and appropriate law enforcement agency.

(7) Notice of a hearing on an urgent suspension shall be served on the clinic by certified mail, return receipt requested, or by personal service.

(8)(a) Within five (5) working days of completion of the hearing, the cabinet's hearing officer shall render a written decision affirming, modifying, or revoking the urgent suspension.

(b) The urgent suspension shall be affirmed if there is substantial evidence of an immediate danger to the public health, safety, or welfare.

(9) The decision rendered under subsection (8) of this section shall be a final order of the agency on the matter, and any party aggrieved by the decision may appeal to circuit court.

(10) If the cabinet issues an urgent suspension, the cabinet shall take action to revoke the clinic's license pursuant to subsection (3) of this section if:

(a) The clinic fails to attend the expedited hearing;

(b) The decision rendered under subsection (8) of this section affirms that there is substantial evidence of an immediate danger to the public health, safety, or welfare; or

(c) Referral to a professional licensing board and law enforcement agency in accordance with subsection (6)(c) of this section results in an administrative sanction or criminal conviction relating to controlled substances against a physician or prescribing practitioner employed by, or under contract with, the clinic.

(11) Pursuant to KRS 216B.050, the cabinet may compel obedience to its lawful orders. (14 Ky.R. 1718; 1923; 2033; eff. 4-14-1988; 18 Ky.R. 866; eff. 10-16-1991; TAm eff. 12-10-2012; 42 Ky.R. 962; 1805; 2139; eff. 2-5-2016; 45 Ky.R. 479, 1026; eff. 11-2-2018.)